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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,956	02/12/2002	Mary Lynne Hedley	08191-022001	6983
26161	7590	10/03/2003	EXAMINER	
FISH & RICHARDSON PC			NGUYEN, DAVE TRONG	
225 FRANKLIN ST			ART UNIT	PAPER NUMBER
BOSTON, MA 02110			1632	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,956	HEDLEY, MARY LYNNE	
	Examiner	Art Unit	
	Dave T. Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, 14-15, 30, drawn to a preventive method of modulating an immune response in a mammal so as to treat a mammal which is at risk for having a bladder disorder, the method comprising administering an isolated nucleic acid comprising an unmethylated CpG sequence, classifiable in class 514, subclass 44.
- II. Claims 19-24, 28, 30, drawn to a preventive method of modulating an immune response in a mammal so as to treat a mammal which is at risk for having a bladder disorder, the method comprising administering an isolated nucleic acid encoding an alpha-MSH polypeptide, classifiable in class 514, subclass 44.

Should Group I or II be elected, wherein the elected invention is identified as a linking claimed invention (claims 1-8, 14-16), a further group restriction is required as follows:

A. Claims 9-11, drawn to a bladder disorder which characterized by inflammation.

B. Claim 13, drawn to bladder disorder which is cancerous.

For Inventions I and II, claims 1-8, 14-16 are identified as the linking claims.

III. Claim 1-11, 13-18, drawn to a therapeutic method of modulating an immune response in a mammal having a bladder disorder so as to treat the mammal, the method comprising administering an isolated nucleic acid comprising an unmethylated CpG sequence, classifiable in class 514, subclass 44.

IV. Claims 19--27, 29, drawn to a preventive method of modulating an immune response in a mammal so as to treat a mammal which is at risk for having a bladder disorder, the method comprising administering an isolated nucleic acid encoding an alpha-MSH polypeptide, classifiable in class 514, subclass 44.

Should Group III or IV be elected, wherein the elected invention is identified as a linking claimed invention (claims 19-24), a further group restriction is required as follows:

C. Claims 25-28 (Invention III), or claims 25-27 (invention IV), drawn to a bladder disorder which characterized by inflammation.

D. Claim 29, drawn to bladder disorder which is cancerous.

For Inventions III and IV, claims 19-24 are identified as the linking claims.

Note that the restriction requirement between the linked inventions is subject to

the nonallowance of the linking claim(s), as listed above. Upon the allowance of the linking claims, the restriction requirement as to the liked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

V. Claims 31-32, drawn to a preventive method of modulating an immune response in a mammal at risk of having a bladder disorder, the method comprising the use of a peptide that binds to a melanocortin receptor in the mammal, classifiable in class 514, subclass 2.

VI. Claims 31-32, drawn to therapeutic method of modulating an immune response in a mammal having a bladder disorder, the method comprising the use of a peptide that binds to a melanocortin receptor in the mammal, classifiable in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV and Inventions V-VI are distinct because inventions I-IV are directed to treatment method of using a nucleic acid, whereas invention V-VI is directed to treatment methods of using a peptide, wherein a peptide and a nucleic acid, respectively, are structurally and functionally distinct. Inventions I-II and Invention III-IV are distinct because the concept of employing a unmethylated CpG nucleic acid is distinct from the concept of using a nucleic acid encoding an alpha-MSH polypeptide. Further, the use of a DNA coding for an alpha-MSH polypeptide is not required in use for inventions I-II, and can be used by itself in the treatment method. Invention I and Invention II, or Invention III-IV are distinct because one is directed to a preventive method wherein a healthy mammal at risk of having a bladder disorder is targeted for the method, and the other is directed to a therapeutic method for use in a mammal already undergoing a symptom of having a bladder disorder. Inventions A and B, or Inventions C and D are distinct because an inflammatory bladder is not the same as a bladder cancer, wherein each of which is directed to a specific disorder which required distinct consideration of prior art and patentability.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, it would be unduly burdensome for the examiner to search and examine for patentability

of all of the claimed inventions, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632


DAVE T. NGUYEN
PRIMARY EXAMINER